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10/608,563	06/30/2003	Christoph Schmidt	MERCK-2715	7256
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ARLINGTON,	VA 22201		1616	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

· ,		А	Application No.	Applicant(s)				
Office Action Summary		1	10/608,563	SCHMIDT ET AL.				
		E	xaminer	Art Unit				
			David P. Stitzel, Esq.	1616				
Period fo	The MAILING DATE of this communi or Reply	ication appear	rs on the cover sheet with the co	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status			·					
- 1)⊠	Responsive to communication(s) file	d on 30 June	<b>⊋ 2003</b> .					
·			ction is non-final.					
3)□	Since this application is in condition	,—		secution as to the merits is				
•	closed in accordance with the practic		· · ·					
Dispositi	on of Claims							
4)🖂	Claim(s) 1-11 is/are pending in the a	pplication.						
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	Claim(s) is/are allowed.							
6)⊠	Claim(s) 1-11 is/are rejected.			· ·				
7)	Claim(s) is/are objected to.							
8)□	Claim(s) are subject to restric	tion and/or el	lection requirement.	İ				
Applicati	on Papers							
9) 🗌 ·	The specification is objected to by the	e Examiner.						
•	The drawing(s) filed on is/are:		ted or b)□ objected to by the E	Examiner.				
	Applicant may not request that any object	ction to the dra	wing(s) be held in abeyance. See	37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) 🔲	The oath or declaration is objected to	by the Exam	niner. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119								
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☐ All b) ☐ Some * c) ☐ None of:</li> <li>1. ☐ Certified copies of the priority documents have been received.</li> <li>2. ☐ Certified copies of the priority documents have been received in Application No</li> <li>3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ul>								
* 0		•		d				
* See the attached detailed Office action for a list of the certified copies not received.								
Attachmen	t(s)							
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Pager No(s)/Mail Date								
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  Paper No(s)/Mail Date  Paper No(s)/Mail Date								

Art Unit: 1616

Examiner: David P. Stitzel, Esq.

#### OFFICIAL ACTION

### Status of Claims

Claims 1-11 are currently pending and therefore examined herein on the merits for patentability.

### Claim Rejections - Nonstatutory Double Patenting

A nonstatutory double patenting rejection of the "obviousness-type" is based on a judicially created doctrine grounded in public policy (a policy reflected in 35 U.S.C. § 101) so as to prevent not only the unjustified or improper timewise extension of the "right to exclude" granted by a patent, but also possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned or assigned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent

Examiner: David P. Stitzel, Esq.

may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* stated that one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court in *Vogel* also pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Number 6,596,070 (hereinafter the Schmidt et al. '070 patent).

The following claims analysis chart sets forth not only the claim limitations (which are drawn to a species) present in the instant application, but also the conflicting claims (which are drawn to a genus) and those corresponding portions of the specification within the disclosure of the Schmidt et al. '070 patent that provide support for the conflicting claims by means of guidance as to what particular species fall within the scope of the claimed genus.

Page 4

Art Unit: 1616 Examiner: David P. Stitzel, Esq.

Patent Application Serial Number 10/608,563; Schmidt et al.; Filed 06/30/03			Schmidt et al.	
Claim	Limitation	Claims	Col.	Lines
1 8	a pigment preparation for use in a cosmetic formulation comprising:	1-12	2	43-67
	a platelet-shaped substrate (S) having a five-layer sequence comprising:		3	40-67
	a tin oxide layer (S1) from 0.1 nm to 50 nm thick;		4	1-56
	a titanium dioxide layer (A) in rutile form from 10 nm to 800 nm thick;		5	29-60
	a colorless coating (B) from 20 nm to 800 nm thick having n ≤ 1.8			
	a tin oxide layer (B1) from 0.1 nm to 50 nm thick;			
	a titanium dioxide layer (C) in rutile form from 10 nm to 800 nm thick; and			
	an optional external protective layer (D).			
2	platelet-shaped substrate (S) is mica, glass, aluminum oxide, silicon	1-3	2	43-67
	dioxide or titanium dioxide.		3	1-3, 40-50
	·		4	8-25
3	colorless coating (B) is aluminum oxide, boehmite, boron oxide, magnesium	1,2,4,6,8,9	3	65-67
	fluoride or silicon dioxide.		4	1-3
4	optional external protective layer (D) increases light, temperature and weather stability.	1,2,12	5	28-35
5 p	process of making a pigment preparation comprising coating a platelet-	10	4	35-59
	shaped substrate via a hydrolytic decomposition of a metal salt present			
	in an aqueous medium.			
6	an intended future use of said pigment preparation	1,2,11	2	52-54
			5	47-50
7	pigment preparation further comprising a binder/filler/extender	1,2	5	58-60
8-10	a dry pigment preparation in the form of a pellet, granule, chip or briquette	1,2	4	51-56
	comprising a moisture content in an amount from 0% to 8% by weight			
11	a cosmetic formulation comprising said pigment preparation	1,2,11	2	52-54
			5	47-50, 58-60

Claims 1-11 of the instant invention are mere obvious variations of claims 1-12 of the Schmidt et al. '070 patent, as one of ordinary skill in the art would have immediately recognized that claims 1-11 of the instant invention are directed to particularly named species that merely fall within the scope of the respective claimed genera, as set forth and disclosed in claims 1-12 of the Schmidt et al. '070 patent.

Art Unit: 1616 Examiner: David P. Stitzel, Esq.

## Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 99/20695 (hereinafter WO '695).

More specifically, claims 1-4 and 8-10 of the instant application are directed to a pigment preparation for use in a cosmetic formulation comprising a platelet-shaped substrate (S) having at least a five-layer sequence comprising:  $(S_1)$  a tin oxide layer having a layer thickness from 0.1 nm to 50 nm; (A) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 800 nm; (B) a colorless coating having a refractive index of  $\leq 1.8$  and a layer thickness from 20 nm to 800 nm; (B<sub>1</sub>) a tin oxide layer having a layer thickness from 0.1 nm to 50 nm; (C) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 800 nm; and optionally (D) an external protective layer; wherein said platelet-shaped substrate (S) is selected from the group consisting of mica, glass, aluminum oxide, silicon dioxide and titanium dioxide; wherein said colorless coating (B) is selected from the group consisting of aluminum oxide, boehmite, boron oxide, magnesium fluoride and silicon dioxide; wherein said external protective layer (D) increases light, temperature and weather stability; wherein said pigment preparation is a dry preparation in the form of a pellet, granule, chip or briquette comprising water in an

Art Unit: 1616 Examiner: David P. Stitzel, Esq.

amount from 0% to 8% by weight of said dry preparation. Claim 5 of the instant application is directed to a process of making a pigment preparation comprising coating a platelet-shaped substrate via a hydrolytic decomposition of a metal salt present in an aqueous medium. Claim 7 of the instant application is directed to a pigment preparation further comprising a binder, filler or extender. Claims 6 and 11 of the instant application is directed to an intended future use of said pigment preparation and as such will be given little probative patentable weight.

Similarly, WO '695 discloses a pigment preparation (title) for use in a cosmetic formulation (page 4, lines 17-19; page 10, lines 4-6; and claim 11) comprising a platelet-shaped substrate (S) having at least a five-layer sequence (abstract; page 4, lines 1-36; page 6, lines 1-9; page 6, lines 35-36; page 7, lines 1-15; and claims 1-3) comprising: (S<sub>1</sub>) a tin oxide layer having a layer thickness from 1 nm to 50 nm (page 6, lines 35-36; page 7, lines 1-10; and claim 2); (A) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 550 nm (abstract; page 4, lines 1-5; page 6, lines 11-22 and 35-36; page 7, lines 1-11; and claims 1, 2, 4, 5, 8 and 9); (B) a colorless coating having a refractive index of < 1.8 and a layer thickness from 10 nm to 1000 nm (abstract; page 4, line 7; page 6, lines 24-28; page 6, lines 35-36; page 7, lines 1-12; and claims 1, 2, 4, 6, 8 and 9); (B<sub>1</sub>) a tin oxide layer having a layer thickness from 1 nm to 50 nm (page 6, lines 35-36; page 7, lines 1-13; and claim 2); (C) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 550 nm (abstract; page 4, line 9; page 6, lines 30-36; page 7, lines 1-14; and claims 1, 2, 4, and 7-9); and optionally (D) an external protective layer (abstract; page 4, line 13; page 7, line 15; and claims 1 and 2); wherein said platelet-shaped substrate (S) is selected from the group consisting of mica, glass, aluminum oxide, silicon dioxide and titanium dioxide (abstract; page 4, lines 21-36; and claims 1-3); wherein said

Page 7

Art Unit: 1616

colorless coating (B) is selected from the group consisting of aluminum oxide, boehmite, boron oxide, magnesium fluoride and silicon dioxide (page 6, lines 24-28; and claims 1, 2, 4, 6, 8 and 9); wherein said external protective layer (D) increases light and weather stability (page 9, lines 19-27; and claims 1 and 2); wherein said pigment preparation is a dry preparation in the form of a pellet, granule, chip or briquette comprising a moisture content in an amount from 0% to 8% by weight of said dry preparation (page 8, lines 7-11). In addition, WO '695 discloses a process of making a pigment preparation comprising coating a platelet-shaped substrate via a hydrolytic decomposition of a metal salt present in an aqueous medium (page 8, lines 1-14; and claims 1, 2 and 10). Furthermore, WO '695 discloses a pigment preparation further comprising a customary binder, filler or extender (page 10, lines 15-17). Finally, WO '695 discloses an intended future use of said pigment preparation in a cosmetic formulation (page 4, lines 17-19; page 10, lines 4-6; and claim 11).

Although WO '695 does not specifically mention a titanium dioxide species that is in rutile form, titanium dioxide exists in only four different forms (i.e., rutile, anatase, brookite and titanium dioxide (B)) and WO '695 does disclose titanium dioxide, which is a titanium dioxide genus that intrinsically encompasses a titanium dioxide species in rutile form. In addition, although WO '695 does not specifically mention a dry pigment preparation that is in the form of a pellet, granule, chip or briquette comprising a moisture content in an amount from 0% to 8% by weight of said dry preparation, WO '695 does disclose drying and calcining the pigment preparation at temperatures between 250°C to 1000°C, which would intrinsically result in a dry pigment preparation that is in the form of a pellet, granule, chip or briquette comprising a moisture content in an amount from 0% to 8% by weight of said dry pigment preparation.

Furthermore, although WO '695 does not specifically mention imparting hydrophilic, hydrophobic or lipophilic properties, per se, to said pigment preparation in a cosmetic formulation, WO '695 does disclose a pigment preparation for use in a cosmetic formulation, wherein said pigment preparation further comprises a customary binder, filler or extender, which intrinsically impart desired (i.e., hydrophilic, hydrophobic or lipophilic) properties to said pigment preparation in a cosmetic formulation (page 10, lines 4-6 and 15-17).

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103. See MPEP § 2112. This same rationale should also apply to product and process claims claimed in terms of function, property or characteristic. *Id.* Where the claimed and prior art products are identical or substantially identical in structure or composition a prima facie case

Page 9

Art Unit: 1616

of either anticipation or obviousness has been established. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *Id.* "The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." See *In re Fitzgerald*, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 195 USPQ 430, 433-34 (CCPA 1977)).

A rejection under 35 U.S.C. § 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristics. See MPEP § 2112. Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. §§ 102 and 103, expressed as a 102/103 rejection. *Id.* "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. § 103 and for anticipation under 35 U.S.C. § 102." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. See MPEP § 2112. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Id.* However, the Examiner must provide a rationale or evidence tending to show inherence. *Id.* "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In re Robertson*, 49

Page 10

USPQ2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Once a reference teaching a product that appears to be substantially identical to the claimed invention forms the basis of a rejection and the Examiner has provided evidence or technical reasoning tending to show inherency, the burden then shifts to the Applicant to show an unobvious difference between the relied upon reference and the claimed invention. See MPEP § 2112. The USPTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product, regardless of whether the rejection is based either on inherency, under 35 U.S.C. § 102, or on prima facie obviousness, under 35 U.S.C. § 103.

## Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1616 Examiner: David P. Stitzel, Esq.

As an alternative ground of rejection, claims 1-11, which contain a few claim limitations that are not disclosed verbatim by WO '695, are hereby rejected under 35 U.S.C. § 103(a) as being obvious in light of WO '695.

Claims 1-11 of the instant application are directed, in relevant part, to a pigment preparation for use in a hydrophilic, hydrophobic or lipophilic cosmetic formulation, wherein said pigment preparation comprises: (A) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 800 nm; (C) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 800 nm; and a binder, filler or extender; wherein said pigment preparation is a dry preparation in the form of a pellet, granule, chip or briquette comprising water in an amount from 0% to 8% by weight of said dry preparation.

Similarly, WO '695 teaches, in relevant part, a pigment preparation for use in a cosmetic formulation (page 10, lines 4-6), wherein said pigment preparation comprises: (A) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 550 nm (abstract; page 4, lines 1-5; page 6, lines 11-22 and 35-36; page 7, lines 1-11; and claims 1, 2, 4, 5, 8 and 9); (C) a titanium dioxide layer in rutile form having a layer thickness from 10 nm to 500 nm (abstract; page 4, line 9; page 6, lines 30-36; page 7, lines 1-14; and claims 1, 2, 4, and 7-9); and a customary binder, filler or extender; wherein said pigment preparation is a dry preparation in the form of a pellet, granule, chip or briquette comprising a moisture content in an amount from 0% to 8% by weight of said dry preparation (page 8, lines 7-11). Furthermore, although WO '695 does not specifically mention imparting hydrophilic, hydrophobic or lipophilic properties, per se, to said pigment preparation in a cosmetic formulation, WO '695 does disclose a pigment preparation for use in a cosmetic formulation, wherein said pigment preparation further

Art Unit: 1616 Examiner: David P. Stitzel, Esq.

Page 12

comprises a customary binder, filler or extender, which intrinsically impart desired (i.e., hydrophobic or lipophilic) properties to said pigment preparation in a cosmetic formulation (page 10, lines 4-6 and 15-17).

Although WO '695 does not specifically mention a titanium dioxide species that is in rutile form, per se, one of ordinary skill in the art would immediately envision a titanium dioxide species in rutile form, as it is well known in the art that titanium dioxide exists in only four limited forms, namely rutile, anatase, brookite and titanium dioxide (B). In addition, although WO '695 does not specifically mention a dry pigment preparation that is in the form of a pellet, granule, chip or briquette comprising a moisture content in an amount from 0% to 8% by weight of said dry preparation, per se, one of ordinary skill in the art would immediately envision a dry pigment preparation that is in the form of a pellet, granule, chip or briquette comprising a moisture content in an amount from 0% to 8% by weight of said dry preparation, especially since WO '695 teaches drying and calcining the pigment preparation at temperatures between 250°C to 1000°C, which would obviously drive off residual moisture thereby resulting in a dry pigment preparation that is in the form of either a dried pellet, granule, chip or briquette comprising a moisture content in an amount from about 0% to about 8% by weight of said dry pigment preparation. Furthermore, although WO '695 does not specifically mention imparting hydrophilic, hydrophobic or lipophilic properties, per se, to said pigment preparation in a cosmetic formulation, WO '695 does disclose a pigment preparation for use in a cosmetic formulation, wherein said pigment preparation further comprises a customary binder, filler or extender, which are well known in the art to impart desired (i.e., hydrophilic, hydrophobic or

Examiner: David P. Stitzel, Esq.

lipophilic) properties to said pigment preparation in a cosmetic formulation (page 10, lines 4-6 and 15-17).

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references.

#### Conclusion

Claims 1-11 are rejected.

#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 7:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about

Art Unit: 1616

Page 14 Examiner: David P. Stitzel, Esq.

acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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